

## **Claim Rejections**

### **35 U.S.C. § 112, first paragraph**

The Examiner has rejected claims 1-10 and 12-18 under 35 U.S.C. § 112, first paragraph, for not providing reasonable enablement for any and all conditions where the metabolism of sphingolipids in a cell needs to be altered. Applicants request that the Examiner consider the following amendments concerning this rejection.

The original claim language read “a method of treating an abnormal condition in a subject associated with an alteration in sphingolipid metabolism”. The Examiner states “it would be an undue burden for one of ordinary skill in the art to test any and all conditions where the metabolism of sphingolipids in a cell needs to be altered”. The Examiner also states that “the specification as filed, is enabled for a method of treating Neimann-Picks syndrome, Tay-Sachs disease, a neoplastic condition or a type of toxicity to the body or cell”. The claims have been amended to read “a method of treating a neoplastic condition or toxicity”.

### **35 U.S.C. § 112, second paragraph**

The Examiner has rejected claims 1-18 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. Applicants request that the Examiner consider the following amendments.

The Examiner states “what does the term, ‘method of altering the metabolism of sphingolipids in a cell’ mean? It is not clear why this would be done or what this would

encompass? How would one know which cells to alter the metabolism of?”. Applicants have canceled claims 1-8, which contain this language.

The Examiner also states “what is meant by abnormal condition in claim 9? This is a very vague and indefinite term”. Applicants have amended claim 9 to remove the term abnormal condition.

### **Additional Claims**

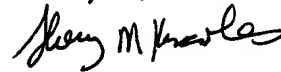
Applicants have added eleven new claims. Claims 47-57 do not include new matter, support for each claim can be found in the specification. Support for claim 47 can be found on page 15, line 36. Support for claim 48 can be found on page 14, line 36. Support for claims 49-52 can be found on page 10, lines 15-19 and in Figure 1. Support for claim 53 can be found on page 9, line 35, page 10, lines 5, 7 and in Figure 1. Support for claim 54 can be found on page 10, lines 5 and 19 and in Figure 1. Support for claims 55-59 can be found on page 10, lines 4-7 and in Figure 1.

**Conclusion**

In light of the amendments and comments presented herein, Applicants request that the Examiner allow all pending claims.

Respectfully submitted,

*By express permission:*



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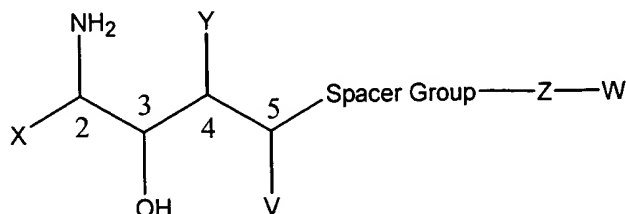

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- **VERSION WITH MARKINGS TO SHOW CHANGES MADE**

9. (amended) A method of treating [an abnormal condition] a neoplastic condition or toxicity in a subject associated with an alteration in sphingolipid metabolism comprising administering an effective amount of a fumonisin[, or an analog thereof, to a subject in a metabolism altering amount] analog of the formula:



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wherein the spacer group is selected from the group consisting of alkyl (straight chain or branched,  $C_1 - C_{20}$ ), hydroxyalkyl (straight chain or branched,  $C_1 - C_{20}$ ) or dihydroxyalkyl (straight chain or branched,  $C_1 - C_{20}$ ); Z is selected from the group consisting of H, O, NH, NQ, NQC(O), NHC(O),  $CO_2$ ,  $C(O)NH$ , and  $C(O)NQ$ , wherein Q is an alkyl (straight chain or branched,  $C_1 - C_6$ ); W is selected from the group consisting of no substituent, H, alkyl (straight chain or branched,  $C_1 - C_6$ ), aryl (phenyl, substituted phenyl such as substitution with alkyl (straight chain or branched,  $C_1 - C_6$ ) or halo),  $C(O)(CH_2)_nCO_2H$  (where  $n = 1 - 6$ ),  $C(O)(CH_2)_nCW'_2CO_2H$ , where  $W'$  is selected independently from H, alkyl (straight chain or branched,  $C_1 - C_6$ ), aryl (phenyl, substituted phenyl such as substitution with alkyl (straight chain or branched,  $C_1 - C_6$ ) or halo), and  $(CH_2)_nCO_2H$ , wherein  $n = 1 - 6$ ; X is selected from the group consisting of H, methyl,  $CH_2OH$  (and esters thereof),  $CH_2NQ'_2$  (where  $Q'$  is selected independently from H, alkyl (straight chain or branched,  $C_1 - C_{20}$ ), and acyl  $C(O)Q''$  where  $Q''$  is an alkyl, straight chain or branched,  $C_1 - C_{20}$ ); and V and Y are independently selected from the group consisting of H or OH (and esters thereof).

11. (amended) The method of Claim 9, wherein [the abnormal condition is selected from the group consisting of] Neimann-Picks syndrome[,] or Tay-Sachs disease[, a neoplastic condition and toxicity] is treated.

12. (amended) The method of Claim 9, wherein the [amount of] fumonisin[, or an analog thereof, which is administered is] analog is administered in an amount between 5 and 500 mg.

13. (amended) The method of Claim 9, wherein the [amount of] fumonisin[, or an analog thereof, which is administered is] analog is administered in an amount between 25 and 75 mg.

14. (amended) The method of Claim 9, wherein [the analog has a hydroxyl group at the first carbon] X is CH<sub>2</sub> OH or an ester thereof.

15. (amended) The method of Claim 9, wherein the fumonisin analog has a 2-amino-3,5-diol head group.

16. (amended) The method of Claim 9, wherein the fumonisin analog is Fumonisin B<sub>1</sub>.

17. (amended) The method of Claim 9, wherein the fumonisin analog is Fumonisin B<sub>2</sub>.